REMARKS

In the Office Action, claims 1, 2, 6-16, 19, 20, 22, and 24 were rejected. By the present Response, claim(s) 1, 6, 12 and 15 are amended. Upon entry of the amendments, claims 1, 2, 6-16, 19, 20, 22, and 24 will remain pending in the present patent application. Reconsideration and allowance of all pending claims are requested.

Rejections Under 35 U.S.C. §112

The Examiner formulated a rejection of claims 1, 6, 12 and 15 under Section 112, First Paragraph, as being failing to comply with the written description requirement, stating that "the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." More specifically, the Examiner objected to the limitations in claim 1, 6, 12, and 15 reciting "wherein the alteration of the medical device software comprises a software upgrade". While not conceding the correctness of the rejection, Applicants have nonetheless amended claims 1, 6, 12 and 15 to remove the objectionable recitation. It is respectfully submitted that the rejection under 35 U.S.C. § 112 is now moot.

Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1, 6, 11-16, and 19-24 under 35 U.S.C. §103(a) as being unpatentable over Yokoi et al., U.S. Patent No. 6,972,565, hereinafter ("Yokoi") in view of Kaseya, V*irtual System Administrator*, hereinafter ("Kaseya"). The Examiner rejected claims 2 and 9 under 35 U.S.C. §103(a) as being unpatentable over Yokoi in view of Kaseya in further view of Krasner, U.S. Patent No. 5,825,327, hereinafter ("Kasner"). The Examiner rejected claim 7 under 35 U.S.C. §103(a) as being unpatentable of Yokoi in view of Kaseya in further view of the manual published by the FDA last revised 01/01/07 entitled "Quality System Manual", hereinafter ("FDA"). The Examiner rejected claims 8 and 10 under 35 U.S.C. §103(a) as

being unpatentable over Yokoi in view of Kaseya in further view of "Reliable Design of Medical Devices" by Richard C. Fries, hereinafter ("Fries"). Applicants respectfully traverse this rejection.

Legal Precedent

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, a claimed invention composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The *KSR* court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does … because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* Specifically, there must be some articulated reasoning with a rational underpinning to support a conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and it must be based on objective evidence of record. *In re Lee,* 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002).

Furthermore, there must be some reason to combine references other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate

the claimed invention. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). The Federal Circuit has warned that the Examiner must not, "fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *In re Dembiczak*, F.3d 994, 999 (Fed. Cir. 1999) (quoting *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)).

In addition, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P. §2145. Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959); *see* M.P.E.P. §2143.01(VI). Further, if the proposed modification or combination would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); *see* M.P.E.P. §2143.01(V).

Deficiencies in the rejection of independent claims 1, 6, 12, and 15

Turning to the claims, amended independent claims 1, 6, 12, and 15 recite in generally similar language, *inter alia*, wherein the medical device is operable to detect an alteration of at least one of medical device hardware and medical device software by a service provider. In the present Office Action, the Examiner rejected claims 1, 6, 12, and 15 citing the combination of Yokoi with Kaseya. However, as discussed below, neither of the cited references alone or in combination, teaches, discloses, suggests or even contemplates such operability.

As the Examiner correctly pointed out, Yokoi does not teach that the medical device is operable to detect an alteration of at least one of medical device hardware and medical

device software. *See* Office Action, pg. 6. Moreover, Kaseya fails to obviate the deficiency of Yokoi. By way of contrast, Kaseya teaches that a monitor may be used to receive "instant notification when … a user removes or adds a PCI card." *See* Kaseya, pg. 2. Assuming, *arguendo*, that Kaseya's Microsoft NT Server teachings would be considered analogous art to a medical device such as an MRI (an assumption that Applicants, in fact, reject), the Kaseya teachings are directed to users only. As the Examiner can appreciate, alterations to such equipment are often highly controlled, as in the case of the claimed servicing, to qualified professional service providers. Indeed, many medical facilities expressly limit the alteration of hardware and software on such equipment to such service personnel. At any rate, such is the specific qualification of the claims.

In addition, amended independent claim 1 recites, *inter alia*, "operating the computer system to generate a service report based on a combination of the medical device data and the service provider data" (emphasis added). The service provider data includes "information related to the alteration of device hardware or software on the medical device by the service provider" (emphasis added). A similar feature is recited by independent claims 6, and 15. Neither Yokoi nor Kaseya teach or even contemplate "operating the computer system to generate a service report based on a combination of the medical device data and the service provider data." Indeed, both the Yokoi and Kaseya fail to enable the claimed subject matter, and in fact, are clearly missing teachings of claim recitations. As mentioned above, Kaseya does not provide any teaching of servicing by service providers. Further, the data in Kaseya's teachings consists of device data only (i.e., Windows NT server or desktop). Yokoi does not obviate this deficiency. A careful review of Yokoi shows that at most, Yokoi teaches the storing of MRI related data (e.g., errors that occur during MRI operations, manufacturer alerts), and not the generating of reports based on a combination of medical device data and the service provider data, where the service provider data includes "information related to the alteration of device hardware or software on the medical device by the service provider."

Accordingly, the Yokoi and Kaseya teachings at the very least fail to enable the claimed subject matter, and indeed fail to disclose each element of the independent claims 1, 6, 12, and 15. For at least these reasons, among others, Applicants submit that Yokoi and Kaseya cannot support a *prima facie* case of obviousness, and that the rejection should be withdrawn. Applicants therefore respectfully request withdrawal of the rejections under 35 U.S.C. § 103 and allowance of claims 1, 6, 12, and 15 as well as those claims depending therefrom.

The remaining secondary references have also been fully reviewed, and also do not obviate the deficiencies of the primary references discussed above.

Conclusion

In view of the remarks and amendments set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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